



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

D1353 B

December 30, 1997

WARNING LETTER

CHI-8-98

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Theodore Mitsakopoulos, President
The Russian Caviar Company
613 West 47th St.
Chicago, IL 60609

Dear Mr. Mitsakopoulos:

We have reviewed labels collected during an inspection of your caviar repackaging operation on June 19, 1997, by the Illinois Department of Public Health.

All of the labeled products currently used on consumer containers of caviar are in violation of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

- All of the labeled products are misbranded in that none of them include the nutritional facts statement as required by Section 403(q)(1) of the Act, in that they fail to bear nutrition labeling as required by Title 21, Code of Federal Regulations (21 CFR), Section 101.9, and are not exempt from this requirement under Section 403(q)(5) of the Act.
- The above products are misbranded within the meaning of 403(i)(2) of the Act, in that the labels fail to bear a statement of ingredients. We understand that caviar is a multicomponent food and a list of ingredients would be required on the label.

The product identified as "Whitefish Caviar" is misbranded within the meaning of Section 403(f) of the Act in that the statement of identity is not prominently placed with such conspicuousness so that it is likely to be read and understood by the ordinary consumer under customary conditions of purchase and use. The identity statement is printed in light yellow ink which is illegible because of the lack of contrast. Furthermore, the identity statement is not declared in a type size reasonably related to the most prominent printed material on the principal display panel (21 CFR 101.3(d)). We note that the identity statement measures approximately 1/32 inch in height, whereas the word "caviar" is six times larger. Generally speaking, FDA considers "reasonably related" to mean at least one-half the size of the most prominent printed material on the label.

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The product identified as "Salmon Caviar" is misbranded within the meaning of Section 403(f) of the Act in that it fails to bear a statement of identity in a type size reasonably related to the most prominent printed matter. The identity statement for this product is not declared on the labels in sufficient prominence and conspicuousness. The type size for "Salmon Caviar" is approximately 1/32 inch in height, whereas the type size for "caviar" is six times as large.

Articles such as these, prepared from the roe of fish other than sturgeon, may be properly labeled "_____ Caviar," the blank to be filled in with the common or usual name of the fish from which the roe was taken.

The violations concern certain new labeling requirements as well as established requirements and are not meant to be an all-inclusive list of deficiencies shown on your labeled products. The violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by the Food and Drug Administration.

You should notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations along with a copy of the revised label. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the correction will be completed.

Your reply should be sent to the attention of Mr. Paul Boehmer, Compliance Officer.

Sincerely,

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Raymond V. Mlecko
District Director